SEP 3 0 2008

510(k) Summary

Fukuda Denshi Model FF Sonic UF-750XT Diagnostic Ultrasound System with option 3D imaging unit (UF-750XT-3DU)

Summary of Safety and Effectiveness
Prepared in accordance with 21 CFR Part 807.92

The assigned 510(k) number is: K082656

Submitter:

Fukuda Denshi USA, Inc.
17725 NE 65th Street, Building C
Redmond, WA 98052
TEL: 425-881-7737
FAX: 425-869-2018

Contact Person:

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17725 NE 65th Street, Building C
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TEL: 425-881-7737
FAX: 425-869-2018

Date Prepared: August 4, 2008

Device Name:

Device Name	Model Number
Fukuda Denshi Model FF Sonic UF-750XT Diagnostic Ultrasound System	UF-750XT
3D imaging Unit	UF-750XT-3DU

Common Name: General Purpose Ultrasound Scanner with Doppler

Classification: Regulatory Class: II
Review Category: Tier II

	CFR Number	Product Code
Ultrasonic Pulsed Doppler Imaging System	892.1550	90-IYN
Ultrasonic Pulsed Echo Imaging System	892.1560	90-IYO
Diagnostic Ultrasound Transducer	892.1570	90-ITX

Marketed Device: The subject device is substantially equivalent in its technologies and functionality to the original Fukuda Denshi Diagnostic Ultrasound System that is already cleared under premarket notification number K#033209, and another predicate device noted below:

Predicate Device	Manufacturer	Model	510(k) Number
First	Hitachi medical	EUB-6500	K#053258

Device Description: The Fukuda Denshi Model FF Sonic UF-750XT Ultrasound System is a general purpose, mobile, software controlled, diagnostic ultrasound system. Its function is to acquire and display ultrasound images in B-Mode, M-Mode, Color mode, PW mode, Power/DirPower mode or the combined mode (i.e. B/M Mode).

The device consists of two parts: the scanner, and one of up to seven (7) different probes. In addition, the probe selector unit provides two probes connection capability. The Fukuda Denshi Diagnostic Ultrasound System is applicable for adults, pregnant women, pediatric patients and neonates, and it is intended for use in abdominal, cardiac, small parts (breast, testes, thyroid, etc.), peripheral vascular, fetal, transvaginal, pediatric, and musculoskeletal (general and superficial) exams.

This subject modified Ultrasound System also provides 3D imaging (Guided free hand 3D and Free hand 3D) with an optional 3D imaging unit (UF-750XT-3DU). New measurement functions have been added by the option 3D imaging unit (UF-750XT-3DU). No new transducers are being added and are not the subject of this submission.

Intended Use: The device is intended to be used for applications in fetal, abdominal, pediatric, small organ (defined as the thyroid, breast and testes, etc.), cardiac (adult and pediatric), transvaginal, peripheral vessel, and musculo-skeletal (Conventional and Superficial). The device incorporates built-in measurement and calculation packages that are to be used by competent health care professionals. The device is a prescription device intended to be use by or on the order of a physician or similarly qualified healthcare professional. The device is intended to be used on any patient; neonate, pediatric, or adult; where the placement and positioning of the transducer does not interfere with or complicate the treatment of the patient. This device is not intended for home use.

Technological Characteristics:

The FF Sonic UF-750XT with option 3D imaging unit (UF-750XT-3DU) incorporates the same fundamental technologies as the predicate devices. The

probes cleared with the predicate device (FF Sonic UF-750XT, K#033209) are used for the subject device. The device has been tested as Track 3 devices per the FDA guidance document "Information for Manufacturers Seeking Clearance of Diagnostic Ultrasound Systems and Transducers" issued in September, 1997. The Acoustic Output is measured and calculated per NEMA UD 2 Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment: 2004. All transducers used with the FF Sonic UF-750XT are track 3 transducers and testing validated that no transducer/system combination exceeded a Thermal or Mechanical Index of 1.0. All patient contact materials are biocompatible and identical to the predicate Fukuda Denshi device.

The technology characteristics of the FF Sonic UF-750XT with option 3D imaging unit (UF-750XT-3DU) do not affect the safety or efficacy of the device. Any safety issues raised by a software controlled medical device are either the same as the issues already addressed by the predicate device or are addressed in the system hazard analysis or in the system validation.

Testing:

Laboratory Testing:
Laboratory testing was conducted to verify that the Fukuda Denshi FF Sonic Model UF-750XT with option 3D imaging unit (UF-750XT-3DU) met all design specification and was substantially equivalent to the current legally marketed predicate devices. The device has been found to conform to applicable medical device safety standards in regards to thermal, mechanical and electrical safety as well as biocompatibility and effectiveness of cleaning and disinfection.

Applicable Standards:
The FF Sonic UF-750XT with option 3D imaging unit (UF-750XT-3DU) conforms to the following Standards:

- NEMA UD 2 Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment: 2004
- NEMA UD 3 Standard for Real-Time Display of Thermal and Mechanical Acoustic Output Indices: 2004
- IEC 60601-1
- IEC 60601-1-1
- IEC 60601-1-2
- IEC 60601-1-4
- IEC 60601-2-37

Clinical Test:
No clinical testing was required

Conclusion:

The conclusion drawn from the testing of the Fukuda Denshi FF Sonic Model UF-750XT Diagnostic Ultrasound system with option 3D imaging unit (UF-

750XT-3DU) demonstrates that the device is as safe and effective as the current legally marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 30 2008

Fukuda Denshi USA, Inc.
% Mr. Robert Mosenkis
President
Citech
5200 Butler Pike
PLYMOUTH PA 19462-1298

Re: K082656
Trade/Device Name: FFsonic UF-750XT Diagnostic Ultrasound System
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: II
Product Code: IYN, ITX, and IYO
Dated: September 11, 2008
Received: September 12, 2008

Dear Mr. Mosenkis:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the FFsonic UF-750XT Diagnostic Ultrasound System, as described in your premarket notification:

Transducer Model Number

FUT-CD602-5A
FUT-CD602-5B
FUT-CD505-8A
FUT-LD386-9A
FUT-CD152-5A

FUT CD105-8A
FUT-TVD114-7A

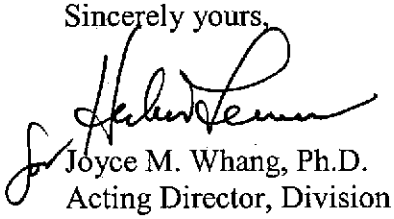
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

If you have any questions regarding the content of this letter, please contact Paul Hardy at (240) 276-3666.

Sincerely yours,



for Joyce M. Whang, Ph.D.
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure(s)

Ultrasound Device Intended Use Form

Fill out one form for each ultrasound system or transducer

Device Name: FFsonic UF-750XT Diagnostic Ultrasound System

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation										
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Harmonic Imaging	Other (Specify)
Ophthalmic											
Fetal		P	P	P		P	P	P	B/M/D/C	P	N
Abdominal		P	P	P		P	P	P	B/M/D/C	P	N
Intraoperative											
Intraoperative Neurological											
Pediatric		P	P	P		P	P	P	B/M/D/C		N
Small Organ (specify)		P	P	P		P	P	P	B/M/D/C		N
Neonatal Cephalic											
Adult Cephalic											
Cardiac		P	P	P		P	P	P	B/M/D/C	P	
Transesophageal											
Transrectal											
Transvaginal		P	P	P		P	P	P	B/M/D/C		
Intravascular											
Peripheral Vessel		P	P	P		P	P	P	B/M/D/C		N
Laparoscopic											
Musculo-skeletal Conventional		P		P							N
Musculo-skeletal Superficial		P		P							N
Other (specify)											

N= new indication for use; P= previously cleared by FDA; E = added under Appendix E

Other Indications or Modes:

In Combined mode: B = B mode, M = M mode, D = Doppler (PWD), C = Color Doppler (including Amplitude Doppler, Color Velocity Doppler)
In Other mode: 3-D Imaging

Small Organ: breast, thyroid, testes, etc.

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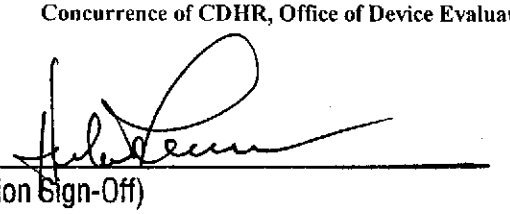
Concurrence of CDHR, Office of Device Evaluation (ODE)



(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K082650

Ultrasound Device Intended Use Form

Fill out one form for each ultrasound system or transducer

Device Name: UF-750XT with FUT-CD602-5A

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation										
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Harmonic Imaging	Other (Specify)
Ophthalmic											
Fetal		P	P	P		P	P	P	B/M/D/C	P	N
Abdominal		P	P	P		P	P	P	B/M/D/C	P	N
Intraoperative											
Intraoperative Neurological											
Pediatric											
Small Organ (specify)											
Neonatal Cephalic											
Adult Cephalic											
Cardiac											
Transesophageal											
Transrectal											
Transvaginal											
Intravascular											
Peripheral Vessel											
Laparoscopic											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other (specify)											

N= new indication for use; P= previously cleared by FDA; E = added under Appendix E

Other Indications or Modes:

In Combined mode: B = B mode, M = M mode, D = Doppler (PWD), C = Color Doppler (including Amplitude Doppler, Color Velocity Doppler)
In Other mode: 3-D Imaging

Small Organ: breast, thyroid, testes, etc.

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Concurrence of CDHR, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K082656

Ultrasound Device Intended Use Form

Fill out one form for each ultrasound system or transducer

Device Name: UF-750XT with FUT-CD602-5B

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation										
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Harmonic Imaging	Other (Specify)
Ophthalmic											
Fetal		P	P	P		P	P	P	B/M/D/C	P	
Abdominal		P	P	P		P	P	P	B/M/D/C	P	
Intraoperative											
Intraoperative Neurological											
Pediatric											
Small Organ (specify)											
Neonatal Cephalic											
Adult Cephalic											
Cardiac											
Transesophageal											
Transrectal											
Transvaginal											
Intravascular											
Peripheral Vessel											
Laparoscopic											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other (specify)											

N= new indication for use; P= previously cleared by FDA; E = added under Appendix E

Other Indications or Modes:

In Combined mode: B = B mode, M = M mode, D = Doppler (PWD), C = Color Doppler (including Amplitude Doppler, Color Velocity Doppler)
In Other mode: 3-D Imaging

Small Organ: breast, thyroid, testes, etc.

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Concurrence of CDHR, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K082656

Ultrasound Device Intended Use Form

Fill out one form for each ultrasound system or transducer

Device Name: UF-750XT with FUT-CD505-8A

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation										
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Harmonic Imaging	Other (Specify)
Ophthalmic											
Fetal		P	P	P		P	P	P	B/M/D/C		N
Abdominal		P	P	P		P	P	P	B/M/D/C		N
Intraoperative											
Intraoperative Neurological											
Pediatric		P	P	P		P	P	P	B/M/D/C		N
Small Organ (specify)											
Neonatal Cephalic											
Adult Cephalic											
Cardiac											
Transesophageal											
Transrectal											
Transvaginal											
Intravascular											
Peripheral Vessel											
Laparoscopic											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other (specify)											

N= new indication for use; P= previously cleared by FDA; E = added under Appendix E

Other Indications or Modes:

In Combined mode: B = B mode, M = M mode, D = Doppler (PWD), C = Color Doppler (including Amplitude Doppler, Color Velocity Doppler)
In Other mode: 3-D Imaging

Small Organ: breast, thyroid, testes, etc.

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Concurrence of CDHR, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K082656

Ultrasound Device Intended Use Form

Fill out one form for each ultrasound system or transducer

Device Name: UF-750XT with FUT-LD386-9A

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation										
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Harmonic Imaging	Other (Specify)
Ophthalmic											
Fetal		P	P	P					B/M		N
Abdominal		P	P	P							N
Intraoperative											
Intraoperative Neurological											
Pediatric		P	P	P		P	P	P	B/M/D/C		N
Small Organ (specify)		P	P	P							N
Neonatal Cephalic											
Adult Cephalic											
Cardiac											
Transesophageal											
Transrectal											
Transvaginal											
Intravascular											
Peripheral Vessel		P	P	P		P	P	P	B/M/D/C		N
Laparoscopic											
Musculo-skeletal Conventional		P		P							N
Musculo-skeletal Superficial		P		P							N
Other (specify)											

N= new indication for use; P= previously cleared by FDA; E = added under Appendix E

Other Indications or Modes:

In Combined mode: B = B mode, M = M mode, D = Doppler (PWD), C = Color Doppler (including Amplitude Doppler, Color Velocity Doppler)
In Other mode: 3-D Imaging

Small Organ: breast, thyroid, testes, etc.

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Concurrence of CDHR, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K082650

Ultrasound Device Intended Use Form

Fill out one form for each ultrasound system or transducer

Device Name: **UF-750XT with FUT-CD152-5A**

Intended Use: **Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:**

Clinical Application	Mode of Operation										
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Harmonic Imaging	Other (Specify)
Ophthalmic											
Fetal		P	P	P		P	P	P	B/M/D/C	P	
Abdominal		P	P	P		P	P	P	B/M/D/C	P	
Intraoperative											
Intraoperative Neurological											
Pediatric											
Small Organ (specify)											
Neonatal Cephalic											
Adult Cephalic											
Cardiac		P	P	P		P	P	P	B/M/D/C	P	
Transesophageal											
Transrectal											
Transvaginal											
Intravascular											
Peripheral Vessel											
Laparoscopic											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other (specify)											

N= new indication for use; P= previously cleared by FDA; E = added under Appendix E

Other Indications or Modes:

In Combined mode: B = B mode, M = M mode, D = Doppler (PWD), C = Color Doppler (including Amplitude Doppler, Color Velocity Doppler)
In Other mode: 3-D Imaging

Small Organ: breast, thyroid, testes, etc.

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Concurrence of CDHR, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K082650

Ultrasound Device Intended Use Form

Fill out one form for each ultrasound system or transducer

Device Name: UF-750XT with FUT-CD105-8A

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation										
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Harmonic Imaging	Other (Specify)
Ophthalmic											
Fetal		P	P	P		P	P	P	B/M/D/C		
Abdominal		P	P	P		P	P	P	B/M/D/C		
Intraoperative											
Intraoperative Neurological											
Pediatric		P	P	P		P	P	P	B/M/D/C		
Small Organ (specify)											
Neonatal Cephalic											
Adult Cephalic											
Cardiac		P	P	P		P	P	P	B/M/D/C		
Transesophageal											
Transrectal											
Transvaginal											
Intravascular											
Peripheral Vessel		P	P	P		P	P	P	B/M/D/C		
Laparoscopic											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other (specify)											

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Other Indications or Modes:

In Combined mode: B = B mode, M = M mode, D = Doppler (PWD), C = Color Doppler (including Amplitude Doppler, Color Velocity Doppler)
In Other mode: 3-D Imaging

Small Organ: breast, thyroid, testes, etc.

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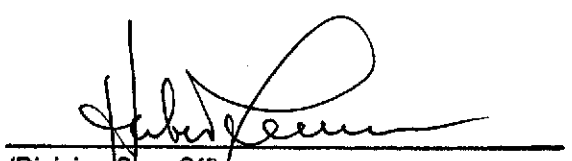

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K082656

Ultrasound Device Intended Use Form

Fill out one form for each ultrasound system or transducer

Device Name: UF-750XT with FUT-TVD114-7A

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation										
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Harmonic Imaging	Other (Specify)
Ophthalmic											
Fetal		P	P	P		P	P	P	B/M/D/C		
Abdominal		P	P	P		P	P	P	B/M/D/C		
Intraoperative											
Intraoperative Neurological											
Pediatric											
Small Organ (specify)		P	P	P		P	P	P	B/M/D/C		
Neonatal Cephalic											
Adult Cephalic											
Cardiac											
Transesophageal											
Transrectal											
Transvaginal		P	P	P		P	P	P	B/M/D/C		
Intravascular											
Peripheral Vessel											
Laparoscopic											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other (specify)											

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Small Organ: breast, thyroid, testes, etc.

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510(k) Number K082656